Exhibit 5 **510(k) Summary**

JAN 1 8 2013

New Device: INNESIS PEEK CAGE

1. Submitter and US Official Correspondent

Submitter: BK MEDITECH CO., LTD.
Address: 215-5 Yodang-ri, Yanggam-myun, Hwasung-si
Gyeonggi-do, 445-930, Korea
Tel: +82-31-352-9135~8
Fax: +82-31-352-9134
Contact: Mr. Byungjun Park, R&D Manager
E-mail: bjpark@bkmeditech.co.kr

US Official Correspondent: Shin Kuk Yoo, Consultant
Telephone No.: 714-313-7442
Fax No.: 801-303-7455
Email: skyone@LSKBioPartners.com

2. Device Information

Proprietary/Trade Name:	INNESIS PEEK CAGE
Common/Usual Name:	Intervertebral body fusion device
Classification Name:	Orthosis, Intervertebral body fusion device
Device Class:	21 CFR section 888.3080
	MAX
	Class II

3. Substantial Equivalence

Substantial equivalence for the INNESIS PEEK Cage is based in its similarities in indication for use, design features, operational principles and material composition when compared to the predicate device cleared under the following submission:

- K050624 - AVSTM PL PEEK Spacer, Stryker Spine Co., Ltd
- K092162 - 4CIS PEEK PLIF Cage System, Solco Biomedical Co. Ltd
- K110067 - LP Cage, Medyssey Co., Ltd

4. Description of Device

The INNESIS PEEK Cage was developed as an implant for the posterior stabilization of the lumbar spinal column using a Posterior Lumbar Interbody Fusion (PLIF) technique and is used in pairs. The INNESIS PEEK implant incorporates ridges on both its superior and inferior surfaces to help eliminate migration. A graft space help facilitate bony integration once

implanted. The implants are made of polyether-ether-ketone (PEEK) body with the x-ray markers made of Titanium alloy (Ti-6A1-4V).

5. Indications for Use

The INNESIS PEEK Cages are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. INNESIS PEEK Cages are to be used with autogenous bone graft and implanted via a posterior approach. The INNESIS PEEK Cages are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. Performance Testing

The testing method for the INNESIS PEEK Cage followed ASTM F2077-11, "Test Methods for Intervertebral Body Fusion Devices."_ASTM F2267-04, "Standard Test Method for Measuring Load Induced Subsidence of_Intervertebral Body Fusion Device Under Static Axial Compression." and ASTM Draft Standard F-04.25.02.02, "Static Push-out Test Method for Intervertebral_Body Fusion Devices," Draft #2 – August 29, 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter dated: January 18, 2013

BK Meditech Co., Ltd.
% LSK Biopartners, Incorporated
Mr. Shin Kuk Yoo
8 East Broadway, Suite 611
Salt Lake City, Utah 84111

Re: K120464
Trade/Device Name: INNESIS PEEK CAGE
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 10, 2012
Received: December 12, 2012

Dear Mr.Yoo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 4 **Indications for Use**

510(k) number (if known): K120464

Device Name: INNESIS PEEK CAGE

Indications for Use:

The INNESIS PEEK Cages are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. INNESIS PEEK Cages are to be used with autogenous bone graft and implanted via a posterior approach. The INNESIS PEEK Cages are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephanie Bechtold -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K120464